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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,473	04/24/2000	Robert N. Hamlin	10527-003007	7841

7590 05/31/2002

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EXAMINER

DYE, RENA

ART UNIT	PAPER NUMBER
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3627

DATE MAILED: 05/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/557,473

Applicant(s)

HAMLIN, ROBERT N.

Examiner

Rena L. Dye

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,28-32 and 34-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,28-32 and 34-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 22, 2002 has been entered.

Claim Rejections - 35 USC 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 44-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrahala (5,248,305).

Zdrahala teaches an extruded catheter and *other flexible plastic tubing* manufactured from a liquid crystal polymer (LCP) (Figure 3; column 2, lines 13-28). The extruded LCP material may be coated, by coextrusion or subsequent extrusion, with a layer of typically non-liquid crystal polymer formulation which has tissue compatible characteristics. Also or alternatively, the coating may be on the inner surface of the tube of liquid crystal polymer material (column 2, lines 28-39). The coating may be a smooth, hemocompatible surface plastic material which may have lubricating characteristics. Coating materials are listed at column 4,

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lines 34-50 and are different materials than that of the LCP. Tubes extruded in accordance with this invention for catheters or any other use may be biaxially oriented in that they may be longitudinally stretched, simultaneously with the rotation of the extrusion die (column 4, lines 55-61).

*Zdrahala further teaches that the tubular catheter body may then have applied to it the customary parts, connections and the like used in the manufacture of conventional catheters of every type (column 4, lines 51-54). Although Zdrahala fails to expressly teach a balloon, it is the Examiner's position that a balloon configured to be attached to a catheter would be included in the teaching of "other flexible plastic tubing" as well as "customary parts, connections and the like." Therefore, it would have been obvious to one having ordinary skill in the art to have made a balloon from LCP as taught by Zdrahala which would meet the limitation of "other flexible plastic tubing", or to have provided a balloon made of LCP to be used in combination with the catheter made of LCP. Since Zdrahala teaches that the LCP is tissue compatible it would have been obvious to one having ordinary skill in the art to have made the customary parts, connections and the like, *or an inflatable balloon*, from the LCP. Since a balloon is generally a tubing as illustrated in Figures 4 and 5 of the present patent application, and Zdrahala teaches extruding of a tubular catheter body, it would have been obvious to one having ordinary skill in the art to have used the process as taught by Zdrahala in making a tube (balloon) which is to be further blow molded into a balloon which is conventionally practiced in the balloon art, followed by attaching or bonding to the catheter body.

Although Zdrahala does not expressly teach the second layer as an adhesion layer, again Zdrahala teaches that the extruded catheter body may then have applied to it the customary parts,

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connections and the like used in the manufacture of conventional catheters of every type (column 4, lines 51-54). Therefore, it would have been obvious to one having ordinary skill in the art to have provided the inner layer with a polymer having adhesive properties so that the catheter could be connected to other parts.

Double Patenting

4. Claims 26,28-32 and 34-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,270,086. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '086. The comprising language recited in independent claim 26 is broad enough to include the recited outer tensile layer and inner bonding layer of '086. Furthermore, '086 defines the outer tensile layer as including LCP (column 2, lines 31-42).

5. Claims 26,28-32 and 34-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 U.S. Patent No. 6,132,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims recited in the present patent application are broad enough to include or overlap with that which is recited in '824. The comprising language recited in independent claim 26 is broad enough to include the recited first layer of a biaxially oriented polymer (polyester) and a second layer or a biaxially oriented polymer (polyolefin).

Allowable Subject Matter

6. Claims 26,28-32,34-39 and 40-43 would be allowable if terminal disclaimers were filed to overcome the obviousness-type double patenting rejections as set forth above.

With respect to claim 26,28-32,34-39, the prior art of record fails to teach or suggest a medical balloon catheter comprising an inflatably expandable balloon configured to be attached to a catheter, the balloon having an extruded layer comprising liquid crystal polymer (LCP), wherein the balloon has a radial expansion less than about 10 percent when inflated to seven atmospheres.

With respect to claims 40-43, the prior art of record fails to teach or suggest a medical balloon catheter comprising an inflatably expandable balloon configured to be carried by a catheter, the balloon having a first extruded layer comprising liquid crystal polymer, and a burst pressure greater than seven atmospheres.

* The Examiner would be willing to allow method claims 44-51 (including claim 52) if Applicant amended the claims to include the balloon having a radial expansion less than about 10 percent when inflated to seven atmospheres, or a burst pressure greater than seven atmospheres, which clearly defines the present claims 44-52 over the Zdrahala reference.

Response to Arguments

7. Applicant's arguments filed on April 22, 2002 have been fully considered.

Applicant's arguments regarding the Zdrahala reference have been addressed in the rejection above. The Examiner has noted that Applicant acknowledges the obviousness-type double patenting rejections over claims in U.S. Patent 5,270,086 and US Application


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No. 08/907,170 (U.S. Patent 6,132,824), and intends to file an appropriate terminal disclaimer upon the indication of allowable subject matter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rena L. Dye whose telephone number is 703-308-4331. The examiner can normally be reached on Monday -Thursday 8:30 AM - 7:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on 703-308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9326 for regular communications and 703-872-9327 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

A handwritten signature in black ink, appearing to read 'Rena L. Dye', with a stylized flourish at the end.

Rena L. Dye
Primary Examiner
Art Unit 3627

R. Dye
May 30, 2002